

PCT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

ST. JUDE MEDICAL AB
Patent Department
S-175 84 Järfälla
SUÈDEDate of mailing (day/month/year)
28 November 2000 (28.11.00)Applicant's or agent's file reference
99 P 2002 P

IMPORTANT NOTIFICATION

International application No.
PCT/SE00/00203International filing date (day/month/year)
01 February 2000 (01.02.00)

1. The following indications appeared on record concerning:

☒ the applicant ☐ the inventor ☐ the agent ☐ the common representative

Name and Address

PACESETTER AB
S-175 84 Järfälla
Sweden

State of Nationality

SE

State of Residence

SE

Telephone No.

+46-8-474 40 00

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☒ the name ☐ the address ☐ the nationality ☐ the residence

Name and Address

ST. JUDE MEDICAL AB
S-175 84 Järfälla
Sweden

State of Nationality

SE

State of Residence

SE

Telephone No.

+46-8-474 40 00

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

The change also applies to the address for correspondence.

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority ☐ other:The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

A. Karkachi

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338.83.38

INTERNET COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C. 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| | |
|--|--|
| Date of mailing (day/month/year) 17 October 2000 (17.10.00) | |
| International application No. PCT/SE00/00203 | Applicant's or agent's file reference 99 P 2002 P |
| International filing date (day/month/year) 01 February 2000 (01.02.00) | Priority date (day/month/year) 25 February 1999 (25.02.99) |
| Applicant MAGNUSSON, Gunnar | |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

01 August 2000 (01.08.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|--|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35 | Authorized officer R. E. Stoffel Telephone No.: (41-22) 338.83.38 |
|--|--|

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|---|---|---|
| Applicant's or agent's file reference 99 P 2002 P | FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. | |
| International application No. PCT/SE 00/00203 | International filing date (<i>day/month/year</i>) 1 February 2000 | (Earliest) Priority Date (<i>day/month/year</i>) 25 February 1999 |
| Applicant Pacesetter AB et al | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (See Box I).
2. ☐ Unity of invention is lacking (See Box II).
3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing
 - ☐ filed with the international application.
 - ☐ furnished by the applicant separately from the international application,
 - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - ☐ transcribed by this Authority.
4. With regard to the title, ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,
 - ☒ the text is approved as submitted by the applicant.
 - ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
Figure No. 5 ☐ as suggested by the applicant. ☐ None of the figures.
☒ because the applicant failed to suggest a figure.
☐ because this figure better characterizes the invention.

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/375

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| A | US 3971388 A (DAVID J. COWDERY), 27 July 1976 (27.07.76), column 1, line 32 - line 50, abstract -- | 1-13 |
| A | US 4071032 A (JOSEPH H. SCHULMAN), 31 January 1978 (31.01.78), column 2, line 13 - line 21, abstract -- | 1-13 |
| A | US 5476496 A (HANS STRANDBERG ET AL), 19 December 1995 (19.12.95), column 1, line 33 - line 53, abstract -- | 1-13 |

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "B" earlier document but published on or after the international filing date
- "I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

5 June 2000

Date of mailing of the international search report

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86

Authorized officer

NIKOLAJ HAUTAVIITA/EE
Telephone No. +46 8 782 25 00

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| A | US 5662692 A (PAUL M. PASPA ET AL), 2 Sept 1997 (02.09.97), column 4, line 20 - line 30, abstract -- | 1-13 |
| D,A | US 4094321 A (RUDOLPH MUTO), 13 June 1978 (13.06.78), abstract -- | 1-13 |
| D,A | US 5480416 A (JOHN GARCIA ET AL), 2 January 1996 (02.01.96), abstract -- | 1-13 |
| D,A | US 5658321 A (TIMOTHY A. FAYRAM ET AL), 19 August 1997 (19.08.97), abstract -- ----- | 1-13 |

INTERNATIONAL SEARCH REPORT
Information on patent family members

02/12/99

International application No.

PCT/SE 00/00203

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|--|--|
| US 3971388 A | 27/07/76 | JP 1216503 C JP 51078088 A JP 58041070 B | 17/07/84 07/07/76 09/09/83 |
| US 4071032 A | 31/01/78 | CA 1097744 A DE 2703628 A,C FR 2357237 A,B IT 1077901 B JP 1347720 C JP 52113084 A JP 61012702 B | 17/03/81 04/08/77 03/02/78 04/05/85 13/11/86 21/09/77 09/04/86 |
| US 5476496 A | 19/12/95 | NONE | |
| US 5662692 A | 02/09/97 | US 5534019 A | 09/07/96 |
| US 4094321 A | 13/06/78 | NONE | |
| US 5480416 A | 02/01/96 | EP 0730480 A JP 9509872 T WO 9609087 A | 11/09/96 07/10/97 28/03/96 |
| US 5658321 A | 19/08/97 | NONE | |

REC'D 04 APR 2001

WIPO

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

2

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|---|--|---|--|
| Applicant's or agent's file reference 99 P 2002 P | | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/SE00/00203 | International filing date (day/month/year) 01/02/2000 | Priority date (day/month/year) 25/02/1999 | |
| International Patent Classification (IPC) or national classification and IPC A61N1/375 | | | |
| Applicant ST. JUDE MEDICAL AB et al. | | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

| | |
|---|--|
| Date of submission of the demand 01/08/2000 | Date of completion of this report 30.03.2001 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized officer Fontenay, P Telephone No. +49 89 2399 2646  |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/SE00/00203

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

Description, pages:

1-10 as published

Claims, No.:

1-13 as published

Drawings, sheets:

1/3-3/3 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE00/00203

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | |
|-------------------------------|------------------|
| Novelty (N) | Yes: Claims 1-13 |
| | No: Claims |
| Inventive step (IS) | Yes: Claims 1-13 |
| | No: Claims |
| Industrial applicability (IA) | Yes: Claims 1-13 |
| | No: Claims |

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/SE00/00203

Re Item V Reasoned statement under Article 35(2) EPC with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 = US-A-5535097

D2 = US-A-5480416

D3 = US-A-5658321

V.1 The subject-matter of claim 1 is new and inventive in the sense of Article 33(2) and 33(3) PCT considering the prior art as presently known.

Document D1 discloses the closest prior art as to the subject-matter of claim 1. It discloses a housing for an implantable tissue stimulating device comprising a first wall (20) having a first generally flat exterior surface (see D1, figures 1-3); a second wall (30) having a second flat exterior surface and a third circumferential wall (10) joining said first and second wall. Said third circumferential wall comprises a first wall section being connected to the first wall and a curved circumferential second wall section being connected to said second wall (see figures 6 and 9). In D1, the first wall is adapted to face the skin of a patient and a curve radius of the first wall section is smaller than the curve radius of the second wall section, for curve radii in planes essentially perpendicular to the first and second surfaces.

The subject-matter of claim 1 differs from said known housing in that the third wall is made of a conductive material.

The objective problem solved by said feature is to avoid unwanted stimulation of muscles in proximity of the flat walls due to concentration of the electric field in these areas.

Said solution is known from document D2 which also relates to cardiac pacemakers (see D2, column 4, lines 49-58). However, The resilient shroud in D1 is essential in order to allow a simplified manufacture of the housing. The

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/SE00/00203

replacement of said shroud by a metallic structure as disclosed in D2 would not permit such a simple manufacturing. It follows that the teaching of D1 leads away from a combination with D2.

The subject-matter of claim 1 is accordingly inventive.

- V.2** The claims 2-13 refer to preferred embodiments of the housing according to claim 1. The subject-matter of claim 1 being considered as new and inventive, the same applies to said preferred embodiments. The subject-matter of claims 2-13 is accordingly also new and inventive

Re Item VII Certain defects in the international application

- VII.1** Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

- VII.2** The general statement in the description, page 8 lines 3-6 suggesting that the extent of protection may be expanded in some vague way should be deleted (Article 6 PCT). The applicant may refer to the Guidelines, PCT/GL/3, Chapter III, § 4.3a.

Re Item VIII Certain observations on the international application

- VIII.1** The subject-matter of claim 1 is not clearly defined (Article 6 PCT).

The wording "said housing being connectable to an electrode lead having an electrode, which is adapted to be in contact with a tissue at a distal end thereof" is not clear because it is not possible to identify the structural limitations as to the housing which should derive from the proposed wording.

The wording "the first wall being adapted to face the skin of a patient" is also vague in that any surface can be considered to be adapted to face the skin of a patient.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

KALLING, Sven
St. Jude Medical AB
Patent Department
SE-175 84 Järfälla
SUEDE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

| | |
|-------------------------------------|------------|
| Date of mailing (day/month/year) | 30.03.2001 |
|-------------------------------------|------------|

| | |
|--|-------------------------------|
| Applicant's or agent's file reference 99 P 2002 P | IMPORTANT NOTIFICATION |
|--|-------------------------------|

| | | |
|---|--|--|
| International application No. PCT/SE00/00203 | International filing date (day/month/year) 01/02/2000 | Priority date (day/month/year) 25/02/1999 |
|---|--|--|

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|---|
| Applicant ST. JUDE MEDICAL AB et al. |
|---|

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

| | |
|---------------------------------------|--------------------|
| Name and mailing address of the IPEA/ | Authorized officer |
|---------------------------------------|--------------------|


| | |
|---|--------------------------------------|
|  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Edel, M Tel. +49 89 2399-2426 |
|---|--------------------------------------|



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | | |
|--|--|---|--|
| Applicant's or agent's file reference 99 P 2002 P | | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/SE00/00203 | International filing date (day/month/year) 01/02/2000 | Priority date (day/month/year) 25/02/1999 | |
| International Patent Classification (IPC) or national classification and IPC A61N1/375 | | | |
| Applicant ST. JUDE MEDICAL AB et al. | | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> | | | |
| <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application | | | |
| Date of submission of the demand 01/08/2000 | | Date of completion of this report 30.03.2001 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized officer Fontenay, P Telephone No. +49 89 2399 2646 | |



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE00/00203

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

Description, pages:

1-10 as published

Claims, No.:

1-13 as published

Drawings, sheets:

1/3-3/3 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

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- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
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3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE00/00203

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | |
|-------------------------------|------------------|
| Novelty (N) | Yes: Claims 1-13 |
| | No: Claims |
| Inventive step (IS) | Yes: Claims 1-13 |
| | No: Claims |
| Industrial applicability (IA) | Yes: Claims 1-13 |
| | No: Claims |

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/SE00/00203

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Reference is made to the following documents:

D1 = US-A-5535097

D2 = US-A-5480416

D3 = US-A-5658321

V.1 The subject-matter of claim 1 is new and inventive in the sense of Article 33(2) and 33(3) PCT considering the prior art as presently known.

Document D1 discloses the closest prior art as to the subject-matter of claim 1. It discloses a housing for an implantable tissue stimulating device comprising a first wall (20) having a first generally flat exterior surface (see D1, figures 1-3); a second wall (30) having a second flat exterior surface and a third circumferential wall (10) joining said first and second wall. Said third circumferential wall comprises a first wall section being connected to the first wall and a curved circumferential second wall section being connected to said second wall (see figures 6 and 9). In D1, the first wall is adapted to face the skin of a patient and a curve radius of the first wall section is smaller than the curve radius of the second wall section, for curve radii in planes essentially perpendicular to the first and second surfaces.

The subject-matter of claim 1 differs from said known housing in that the third wall is made of a conductive material.

The objective problem solved by said feature is to avoid unwanted stimulation of muscles in proximity of the flat walls due to concentration of the electric field in these areas.

Said solution is known from document D2 which also relates to cardiac pacemakers (see D2, column 4, lines 49-58). However, The resilient shroud in D1 is essential in order to allow a simplified manufacture of the housing. The

replacement of said shroud by a metallic structure as disclosed in D2 would not permit such a simple manufacturing. It follows that the teaching of D1 leads away from a combination with D2.

The subject-matter of claim 1 is accordingly inventive.

- V.2** The claims 2-13 refer to preferred embodiments of the housing according to claim 1. The subject-matter of claim 1 being considered as new and inventive, the same applies to said preferred embodiments. The subject-matter of claims 2-13 is accordingly also new and inventive

Re Item VII Certain defects in the international application

- VII.1** Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

- VII.2** The general statement in the description, page 8 lines 3-6 suggesting that the extent of protection may be expanded in some vague way should be deleted (Article 6 PCT). The applicant may refer to the Guidelines, PCT/GL/3, Chapter III, § 4.3a.

Re Item VIII Certain observations on the international application

- VIII.1** The subject-matter of claim 1 is not clearly defined (Article 6 PCT).

The wording "said housing being connectable to an electrode lead having an electrode, which is adapted to be in contact with a tissue at a distal end thereof" is not clear because it is not possible to identify the structural limitations as to the housing which should derive from the proposed wording.

The wording "the first wall being adapted to face the skin of a patient" is also vague in that any surface can be considered to be adapted to face the skin of a patient.

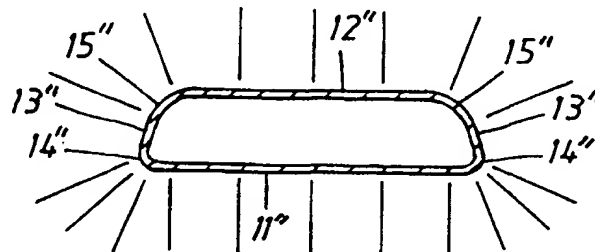
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|--|-----------|--|
| (51) International Patent Classification 7 : A61N 1/375 | A1 | (11) International Publication Number: WO 00/50120 (43) International Publication Date: 31 August 2000 (31.08.00) |
| <p>(21) International Application Number: PCT/SE00/00203</p> <p>(22) International Filing Date: 1 February 2000 (01.02.00)</p> <p>(30) Priority Data: 9900682-7 25 February 1999 (25.02.99) SE</p> <p>(71) Applicant (for all designated States except US): PACESETTER AB [SE/SE]; S-175 84 Järfälla (SE).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): MAGNUSSON, Gunnar [SE/SE]; Orrfjärdsgränd 7, S-120 51 Årsta (SE).</p> <p>(74) Common Representative: PACESETTER AB; Patent Department, S-175 84 Järfälla (SE).</p> | | <p>(81) Designated States: US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> |

(54) Title: IMPLANTABLE TISSUE STIMULATING DEVICE

(57) Abstract

A housing (1") for an implantable tissue stimulating device is disclosed. The housing (1") is connectable to an electrode lead (3") having an electrode, which is adapted to be in contact with a tissue, at a distal end thereof. When implanted, the housing (1") is acting as an electrode and shaped so as to create low strength electric fields in regions where unwanted stimulation of muscles can occur.



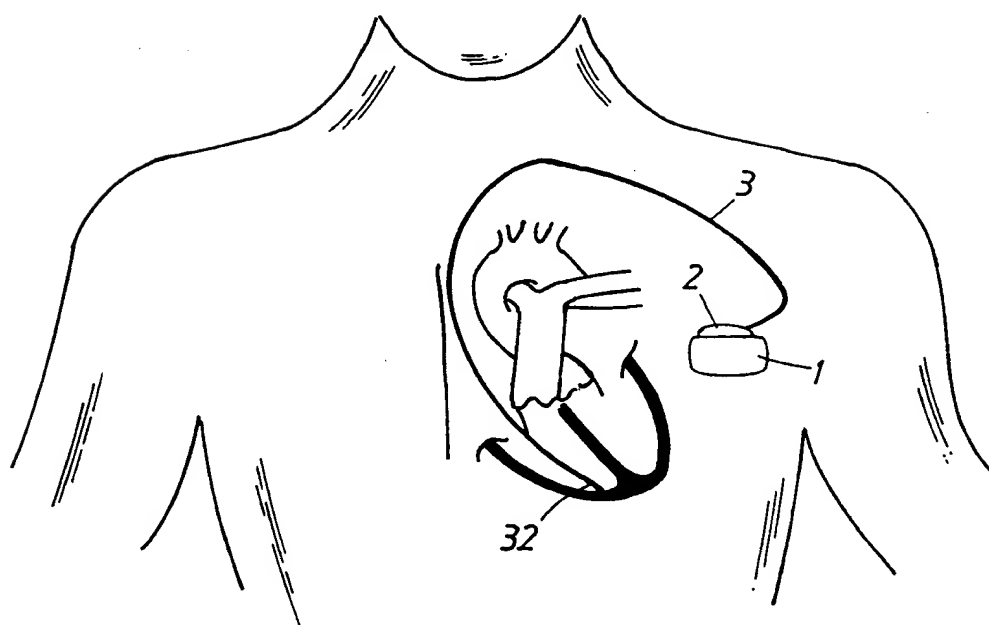
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Fig. 1



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Fig. 2

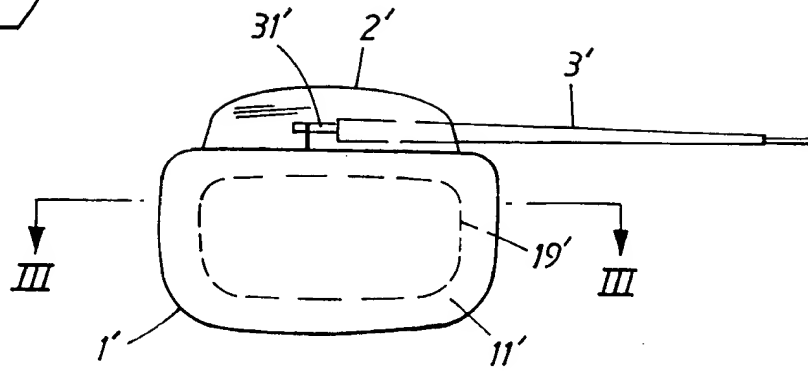


Fig. 3

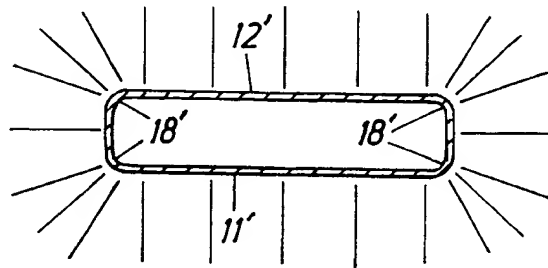


Fig. 4

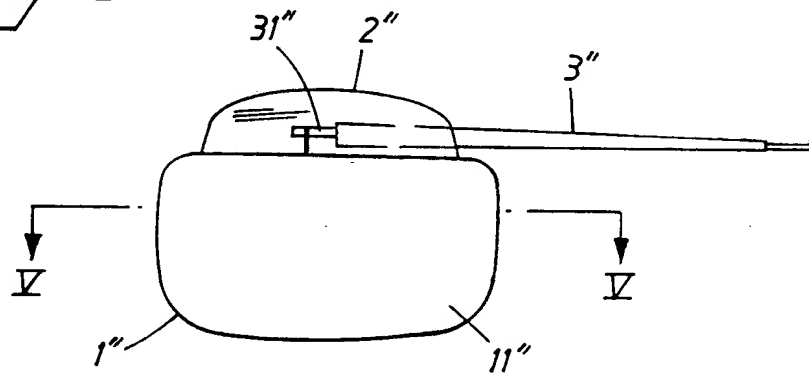


Fig. 5

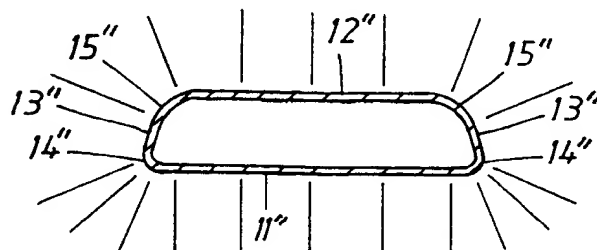


Fig. 6

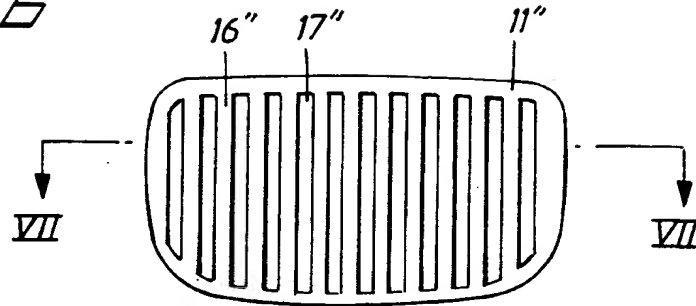


Fig. 7

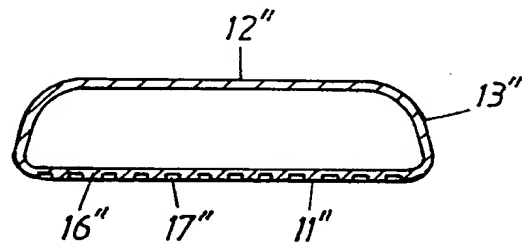


Fig. 8

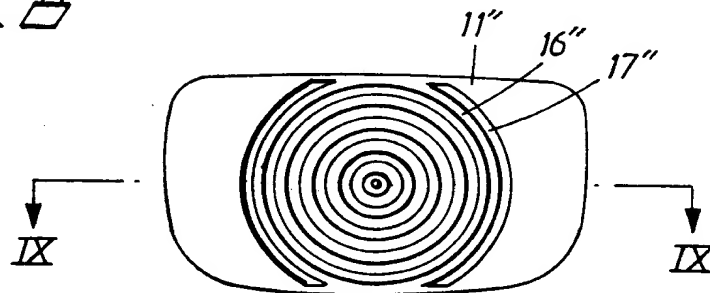
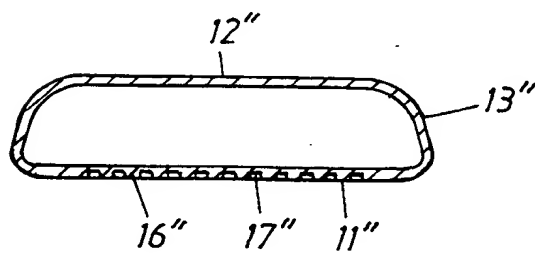


Fig. 9



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/00203

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/375

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| A | US 3971388 A (DAVID J. COWDERY), 27 July 1976 (27.07.76), column 1, line 32 - line 50, abstract -- | 1-13 |
| A | US 4071032 A (JOSEPH H. SCHULMAN), 31 January 1978 (31.01.78), column 2, line 13 - line 21, abstract -- | 1-13 |
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Date of the actual completion of the international search

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Date of mailing of the international search report

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Information on patent family members

02/12/99

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